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Mahe, e Express Mail Label No. | EE718927925US ADDRESS TO: **Assistant Commissioner for Patents** Box Patent Application Washington, DC 20231 6. Microfiche Computer Program (Appendix) Fee Transmittal Form (attached hereto in duplicate) 7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. Computer Readable Copy b. Paper Copy (identical to computer copy) - Cross References to Related Applications c. Statement verifying identity of above copies - Statement Regarding Fed sponsored R&D ACCOMPANYING APPLICATION PARTS 8. Assignment Papers (cover sheet & document(s)) 9. 37 CFR 3.73(b) Statement (when there is an assignee) Power of Attorney 10. English Translation Document (if applicable) 11. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations [Total Sheets 2] 12. Preliminary Amendment 13. Return Receipt Postcard (MPEP 503) (Should be specifically itemized) 14. Certified Copy of Priority Document(s) c. Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional check boxes 5 and 16) (if foreign priority is claimed) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 15. Other: The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein. 16. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information: Amend the specification by inserting before the first line: -- This is a ☐ Continuation ☐ Divisional , filed Continuation-in-Part (CIP) of prior application No.: For this divisional application, please cancel original Claims of the prior application before calculating the filing 17. fee. 18. CORRESPONDENCE ADDRESS or X Correspondence Address below ☐ Customer Number or Bar Code Label Audley A. Ciamporcero, Jr., Esq. Name: Address: Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 USA 19. TELEPHONE CONTACT Please direct all telephone calls or telefaxes to Andrea L. Colby at: Telephone: (732) 524-2792 Fax: (732) 524-2808 19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED Reg. No. 30,194 NAME Andrea L. Colby SIGNATURE Januarv 19. 2000 DATE

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mahe, Joetzjer, Guise

For : A Cosmetic Composition Based on Menthol and Menthyl

Lactate, Haaving Little Odor and Being Non-

Irritating

### Express Mail Certificate

"Express Mail" mailing number: EE718927925US

Date of Deposit: January 19, 2000

I hereby certify that this complete application, based on French application 9900704, filed January 22, 1999, including specification pages, claims, and informal drawings, Utility Patent Application Transmittal and unsigned Declaration/Power of Attorney are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Alwin M. Haywood

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A COSMETIC COMPOSITION BASED ON MENTHOL AND MENTHYL LACTATE, HAVING LITTLE ODOR AND BEING NON-IRRITATING

5 The present invention relates to a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the 10 menthol is barely perceptible, said composition possessing the advantage of not being irritating, in particular for the sensitive parts of the human body, while conserving the various beneficial effects of menthol.

Menthol is a compound well known to the person skilled in the art for its analgesic, freshening, and odoriferous properties, and it has often been used in cosmetic and pharmaceutical products. In addition, this substance is used as flavoring in numerous preparations for alimentary use or indeed in toothpastes.

As recommended by the Food and Drug Administration (FDA), an effective quantity of menthol in a composition must lie in the range 1.25% to 16%. Nevertheless, at such concentrations, the flavor and the odor of the substance are very powerful, and that is poorly appreciated by consumers. In addition, this power is illustrated by the fact that menthol has been used in industrial methods for manufacturing refrigerant products (FR 74/27045).

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Concerning cosmetic compositions, there are numerous compounds capable of giving rise to a cooling effect on the skin. For example, patent DE 24 05 900 describes a composition containing menthol, camphor, and alcohol for

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preparing a slimming composition designed to induce metabolization of skin fat by cooling. SU 15 60 215 relates to a composition for treating gingivitis which contains an association of camphor, menthol, thymol, and salicylic acid. CN 90 10 88 731 relates to a composition for repelling mosquitos and comprising, in particular, menthol and camphor.

Compositions specifically based on menthol are described in the documents of the prior art. Nevertheless, given the overwhelming power of menthol, various esters of menthol have been prepared for the purpose of reducing the odoriferous properties of this substance, but most of such esters possess odors that are very disagreeable, making them unusable in products for local application. In order to obtain satisfactory effectiveness of their analgesic or anti-irritant action, said derivatives are required in quantities that are large. Thus, with an effective quantity of menthol derivatives, said odors constitute a serious obstacle for use as a cosmetic.

One of said derivatives, menthyl lactate, is used in pharmaceutical compositions for oral administration for treating diseases such as respiratory deficiencies, the common cold, sinusitises, bronchitises, or asthma. The beneficial properties of menthyl lactate are set out, for example, in WO 97/42945.

has also been used in cosmetic Menthyl lactate freshener. 30 compositions for local application a as According to the manufacturers, that compound does not produce the mint odor which characterizes most other menthol derivatives.

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Generally, the compound is at concentrations lying in the range 0.1% to 10% in most cosmetic compositions. For example, WO 96/14840 describes analgesic compositions comprising up to 9% menthyl lacate, and US 5 602 178 relates to bath products that have no menthol, containing about 6% menthyl lactate. JP 06329528 and JP 10231238 relate to compositions comprising menthol and menthyl lactate in ratios of 1/1 and 2/1 respectively, however at those ratios, those compositions do not deal with the problems associated with the secondary effects of menthol.

Some of the compositions described in the prior art documents can also contain fragrance reproducing the odor of mint. At low levels, mint odor also contributes to the sensation of cooling provided by menthyl lactate. Nevertheless, some of those fragrances can be expensive, and can give rise to other problems of skin tolerance.

freshening composition, in particular a composition for cleaning the body, which is freshening and not irritating, and which also feels pleasant and provides a slight odor of freshness. One of the difficulties thus lies in developing a freshening composition based on menthol and on its derivatives while keeping the mint odor at a level that is sufficiently low. This makes it possible, optionally, to add other freshening fragrances that are less powerful and non-irritating.

Thus, no document of the prior art describes or suggests the present invention as defined here-below.

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#### Description

The present invention provides a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body. This object is more particularly achieved with a menthol / menthyl lactate ratio lying in the range 1/6 to 1/4. Preferably, the ratio is set at about 1/5, and the composition of the invention comprises 0.1% to 0.5% by weight of menthyl lactate.

Advantageously, the composition comprises 0.08% to 0.12% by weight of menthol and 0.45% to 0.55% of menthyl lactate.

No irritation spoils the beneficial freshening effect obtained by associating menthol and menthyl lactate in the concentrations and ratios specified above.

In addition, the "mint" odor due to the menthol is only faintly perceptible, so the composition can further include at least one fragrance, that can be different from or similar to the fragrance of "mint". In this respect, particular mention can be made of the fragrance "glacier SG 809 A" which reproduces the feeling and the odor of freshness at a concentration of 0.5% to 5% by weight, but without being overpowering and/or irritating.

The general formula of menthyl lactate is as follows:

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This compound contains four asymmetrical carbon atoms. It therefore exists in 16 different stereoisomers. In the context of the invention, the term "menthyl lactate" thus covers not only all such stereoisomers, but also any racemate or mixture of said stereoisomers.

The composition of the invention can also comprise at surface-active agent selected from anionic least one surface-active agents, preferably sodium cocoyl isethionate, at a concentration in the range 1% to 10% by weight, at least one thickening agent selected particular from xantham gums, carbomers, preferably hydroxypropyl methylcellulose at a concentration lying in the range 0.2% to 10% by weight, and at least one conditioning polymer at a concentration lying in the range 0.25% to 2% by weight.

The said composition can also comprise a lustering agent, preferably a mixture of sodium laureth sulfate and of glycol distearate, at a concentration lying in the range 0.1% to 1% by weight, a foaming agent, preferably lauryl betaine, at a concentration lying in the range 1% to 10% by weight, an association of surface active agents such as

betaine, at a concentration lying in the range 1% to 10% by weight, an association of surface active agents such as sodium laureth sulfate, ammonium laureth sulfate, lauryl glucoside, such that the total concentration of surface active agent in the composition lies in the range 5% to 30%, and preferably in the range 15% to 25% by weight, and/or at least one hydrating agent, in particular glycerol and/or polyethylene glycol, at a concentration lying in the range 1% to 20% by weight.

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Naturally, the composition of the invention is not limited to the ingredients mentioned above. For example, it can also contain a buffer, a dye, an anti-oxidant, and/or a preservative.

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In a preferred implementation of the present invention, the composition is intended for use as a shower gel.

In this case, the composition of the invention may have the following compounds in percentage by weight:

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	- Water	62,92 %
	- Sodium laureth sulfate	12 %
	- Hydroxypropyl methylcellulose	0,5 %
	- Sodium cocoyl isethionate	7 %
25	- Ammonium lauryl sulfate	3 %
	- Lauryl glucoside	1 %
	- Lauryl betaine	4 %
	- Polyquaternium-10	5 %
	- Polyethylene glycol (PEG)	2 %
30	- Preservative(s)	0,5 %
	- Fragrance	1,5 %
	- Menthyl lactate	0,5 %
	- Menthol	0,08%

The present invention also provides the use of the abovedefined composition as a product for washing with, in particular as a two-in-one product for simultaneously cleaning and freshening the skin, in particular as a shower gel or as a foaming gel for the face.

10 Example 1: freshening shower gel with pH 5.5

The preferred shower gel of the invention comprises the following compounds in percentage by weight:

	Compounds	% Activity	% by weight	% by weight active
15	- Water		62,92	
	- Sodium laureth sulfate	70	12	8,4
	- Hydroxypropyl methylcellulose	100	0,5	0,5
	- Sodium cocoyl isethionate	100	7	7
	- Ammonium lauryl sulfate	70	3	2,1
20	- Lauryl glucoside	50	1	0,5
	- Lauryl betaine	30	4	1,2
	- Polyquaternium-10	10	5	0,5
	- Polyethylene glycol (PEG)	100	2	2
	- Preservative(s)	100	0,5	0,5
25	- Fagrance	100	1,5	1,5
	- Menthyl lactate	100	0,5	0,5
	- Menthol	100	0,08	0,08

Example 2: comparison of the feeling of freshness

30 obtained with various products (refreshing shower gel at pH 5.5)

Table 1: Products tested

Experimental protocol (blind test):

Product	Isopulegol	Menthol	Menthyl lactate	"Glacier" fragrance
A	0.5%	0.08%		0.5%
В		0.08%	0.5%	1.0%
С		0.1%	0.25%	1.5%
D		0.08%	0.25%	2%

Products A, B, C, and D were applied to the feet of individuals in a confidential study. 1 ml of each product was spread over the total surface area of a foot, and contact with the product was set at 2 minutes. The

contact with the product was set at 2 minutes. The product was then rinsed off using warm water, and the feet were dried. The control used in this study consisted in immersing the other foot in water at ambient temperature, and also in water at 4°C for checking the "very cold" parameter. The test was repeated every day for several

15 days.

The refreshing effect of said compositions was evaluated on a linear scale going from 0 (no effect) to 120 (very cold, like ice). This assessment was made immediately after the product had been applied (TO), after the feet had been rinsed and dried (TO'), and then every minute for 5 minutes. In addition to this assessment, an objective evaluation was performed by measuring the temperature of the skin of the feet.

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The results are given in Tables 2 and 3 below and in Figures 1 and 2 hereafter.

Table 2: Cooling effect compared with control

	то	то'	Т1	Т2	Т3	Т4	Т5
A	33.8	33.3	31.8	28.8	25.3	25.3	22.8
В	24.6	33.5	32.7	34.9	22.5	18.2	20.2
С	31	35.6	24	22.3	15.7	16.5	17.7
D	9.8	16.1	16.4	11	8.6	7.5	3

Table 3: Temperature variation relative to control

	TO	TO	Tl	Т2	Т3	Т4	Т5
A	-0.3	-1	-1.2	-1.1	-0.9	-0.7	-0.6
В	-0.02	-0.66	-0.8	-0.9	-0.8	-0.8	-0.7
С	0.16	-0.79	-1.2	-1.2	-1.3	-1.3	-0.9
D	0.25	-0.08	-0.9	-0.9	-0.9	-0.7	-0.7

The result of this study shows that the optimum composition for obtaining the cooling effect corresponds to a menthol / menthyl lactate ratio set at about 1/5, with a menthol content by weight of about 0.08% to 0.1% and a menthyl lactate content by weight of 0.5%.

# Example 3: study on how the odor of the composition was assessed

This study set out to determine the optimum ratio between the "mint" scent and the "Glacier" scent in above-described compositions A, B, C, and D. It appears clearly from the assessment of the panel that the "mint" odor, which is very powerful, can give rise to negative feelings above a certain level. This difficulty is eliminated by the menthol / menthyl lactate ratios of the invention, and also by adding the "Glacier" fragrance.

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#### Example 4: in vitro study of eye irritation

Various formulations of the refreshing shower gel type composition having pH 5.5 have been tested to determine potential for irritating the eyes at various concentrations and ratios of menthol and menthyl lactate. The results are given in Table 4 below.

Table 4

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Ingredient	Hetcam 5%	Hetcam 1%
Menthol 0.08%	9.0 ± 2.0	6.0 ± 2.3
	Irritant	Moderately
		irritant
Menthol 0.08%	8.0 ± 0.0	4.0 ± 0.0
Menthyl lactate	Moderately	Slightly irritant
0.5%	irritant	
Menthol 0.1%	8.0 ± 0.0	4.0 ± 2.5
Menthyl lactate	Moderately	Slightly irritant
0.5%	irritant	

The combinations menthol 0.08% + menthyl lactate 0.5% and menthol 0.1% + menthyl lactate 0.5% which are effective for refreshing the skin are well tolerated by the most sensitive parts of the body.

## Example 5: study concerning skin tolerance

This study was performed to show that the skin tolerates repeated application of the shower gels of the invention. Shower gels as described above, and also baby shampoo used as a reference, were applied to the antero-internal faces of the forearms.

The skin state of the application zone was verified and then humidified lightly using cotton wool moistened with warm water prior to applying the gels by massage that lasted for 10 seconds. A first reading was taken at T=2 minutes. After rinsing in warm water and drying (using absorbant tissue paper), a second reading was performed at T=10 minutes.

Every day the same application was repeated, and a new reading taken.

The results show that no undesirable effect (no burning sensation, no tingling, no itching, no erythema) occurred after using shower gels of the invention.

#### <u>CLAIMS</u>

1. A freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body.

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- 2. A composition according to claim 1, characterized in that the menthol / menthyl lactate ratio lies in the range 1/6 to 1/4, and is preferably about 1/5.
- 15 3. A composition according to claim 1 or 2, characterized in that it comprises 0.01% to 0.5% by weight of menthol and 0.25% to 1% by weight of menthyl lactate, preferably 0.08% to 0.12% by weight of menthol and 0.45% to 0.55% by weight of menthyl lactate.

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4. A composition according to any one of claims 1 to 3, characterized in that it further includes at least one fragrance, in particular the "glacier SG 809 A" fragrance, at a concentration lying in the range 0.5% to 5% by

25 weight.

- 5. A composition according to any one of claims 1 to 4, characterized in that it further comprises at least one surface active agent selected from anionic surface active agents, preferably sodium cocoyl isethionate, at a concentration lying in the range 1% to 10% by weight.
- 6. A composition according to claim 5, characterized in that it further comprises at least one thickening agent

selected in particular from xanthan gums, carbomers, preferably hydroxypropyl methylcellulose, at a concentration lying in the range 0.2% to 10% by weight.

- 7. A composition according to claim 5 or 6, characterized in that it further comprises at least one conditioning polymer.
- 8. A composition according to any one of claims 5 to 7, characterized in that it further comprises a lustering agent, preferably a mixture of sodium laureth sulfate and of glycol distearate, at a concentration lying in the range 0.1% to 1% by weight.
- 9. A composition according to any one of claims 5 to 8, characterized in that it further comprises a foaming agent, preferably lauryl betaine, at a concentration lying in the range 1% to 10% by weight.
- 10. A composition according to any one of claims 5 to 9, characterized in that it further comprises an association of surface active agents such as sodium laureth sulfate, ammonium laureth sulfate, lauryl glucoside, such that the total concentration in surface active agent in the composition lies in the range 5% to 30%, and preferably in the range 15% to 25%, by weight.
- 11. A composition according to any one of claims 5 to 10, characterized in that it further comprises at least one hydrating agent, in particular glycerol and/or polyethylene glycol, at a concentration lying in the range 1% to 20% by weight.

- 12. A composition according to any one of claims 5 to 11, characterized in that it further comprises at least one buffer, a dye, an anti-oxidant, and/or a preservative.
- 5 13. A composition according to any one of claims 5 to 12, for use as a shower gel.
  - 14. A composition according to any one of claims 5 to 13, characterized in that it comprises the following compounds

10 in percentage by weight:

	- Water	62,92 %
	- Sodium laureth sulfate	12 %
	- Hydroxypropyl methylcellulose	0,5 %
	- Sodium cocoyl isethionate	7 %
15	- Ammonium lauryl sulfate	3 %
	- Lauryl glucoside	1 %
	- Lauryl betaine	4 %
	- Polyquaternium-10	5 %
	- Polyethylene glycol (PEG)	2 %
20	- Preservative(s)	0,5 %
	- Fragrance	1,5 %
	- Menthyl lactate	0,5 %
	- Menthol	0,08%

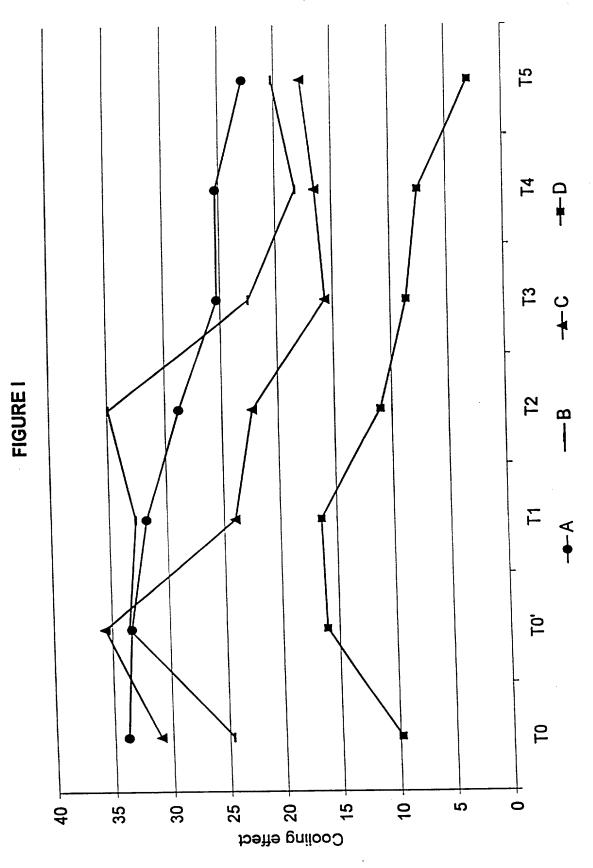
- 15. The use of the composition according to any one of claims 1 to 14, as a bathing product, in particular as a two-in-one product for simultaneously cleansing and freshening the skin.
  - 16. A use according to claim 15 as a shower gel.
  - 17. A use according to claim 15 as a foaming gel for the face.

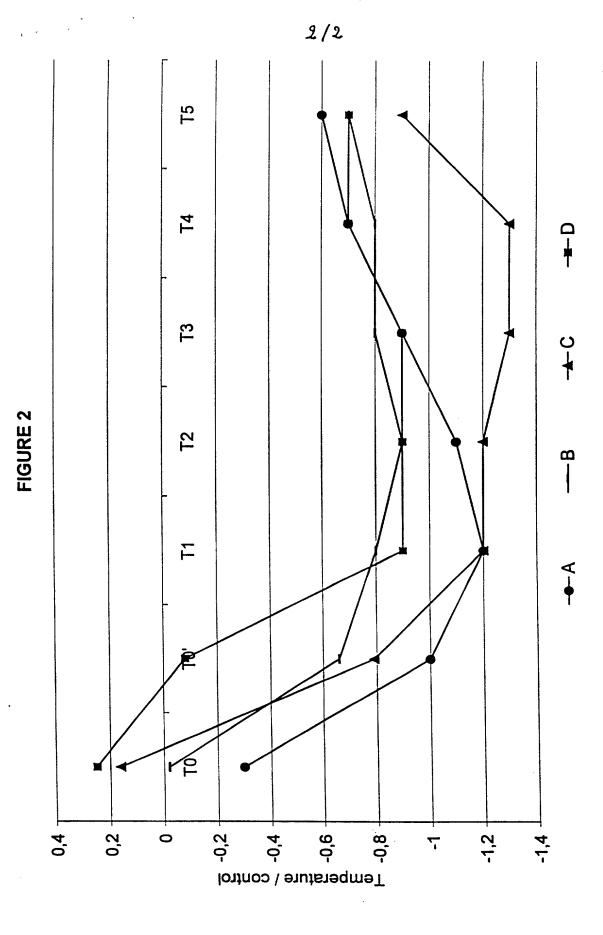
# ABSTRACT

The present invention provides a freshening cosmetic composition characterized in that it comprises 0.01% to 2% by weight menthol and 0.1% to 10% by weight menthyl lactate, the menthol / menthyl lactate ratio lying in the range 1/3 to 1/10, and being such that the odor of the menthol is barely perceptible, said composition not being irritating, in particular for the sensitive parts of the human body, while conserving the various beneficial effects of menthol.

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#### DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled A COSMETIC COMPOSITION BASEF ON MENTHOL and MENTHYL LACTATE, HAVING LITTLE ODOR AND BEING NON-IRRITATING, the specification of which

(check one)	igties is attached hereto.
	was filed on as
	Application Serial No
	and was amended on (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United **§**119 (a) - (d) §365(b) States Code, orof any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

## Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority ( Under 35 U	
France	9900704	January 22, 1999		□ NO
			☐ YES	□ NO
	·		YES	☐ NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
Application Serial No.	Filing Date	Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194) and Michael Stark (Reg. #32,495), One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(Supply similar information and signature for fourth and subsequent joint inventors.)

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